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EXAMINER

EASHOO, MARK

ART UNIT

PAPER NUMBER

1732

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,775

Applicant(s)

GOODE ET AL.

Examiner

Mark Eashoo, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 15-20 and 23 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/02
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The initialed copy of the IDS filed 02-MAY-2002 mailed with the prior Office action did not appear to have considered Bouton et al. A new copy of the IDS, with consideration of Bouton et al., accompanies this Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-20 are rejected under 35 U.S.C. 102(b) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) when taken with Vance, Jr. (*Insert Molding* – Article).

Regarding claim 15: Hirsch et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft (elements 21, 42, 57) having rigidity and resists bending while in use (5:61-6:27 and Fig. 10); and forming a flange by insert molding (elements 31-32) onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (4:11-43 and Fig. 1-5). Hirsch et al. teaches that the hollow tubular shaft has a durometer in the range of 30-40 Shore A (6:10-17) and that the flexible connection flange portions have a durometer of 10-40 Shore A (4:31-39). Since the hardness range of the flange extends well below that of the tube, Hirsch et al. meet the instantly claimed limitation directed to material hardness.

Hirsch et al. specifically recites that the flanges and tubular portion may be attached to one another by insert molding (4:58-62). Vance Jr., provides evidence that 'insert molding' is a molding technique where a preform is inserted into a mold and another material is injection molded to encapsulate a portion of the preform. Vance Jr. states that insert molding is used quite

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extensively in the manufacture of medical devices, such as "insert molded needles hubs". A person having ordinary skill in the art would clearly understand that the hub is by the injected material. It is also noted that the flange structure of Hirsch et al. encapsulates an end portion of a tube (Fig. 3 and 8).

Regarding claims 16 and 17: Hirsch et al. teaches attaching the flange to the tube by insert molding (4:55-62). Since the flange encapsulates, surrounds and encompasses a portion of the tube (Fig. 3 and 8), it is inherent as evidenced by Vance Jr., that the tube is first placed in the mold and the material forming the flange is then injected into the mold.

Regarding claim 18: Hirsch et al. teaches a flange/second material in the range of 10-40 Shore A (4:30-40), of which the upper portion of this range is "about 50".

Claim 23 is also rejected under 35 USC 102(b), but for convenience the rejection has been written in the alternative below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) in view of Bodicky (US Pat. 4,354,495) and Vance, Jr. (*Insert Molding* – Article). *This is an alternative rejection assuming Hirsch et al. does not teach 'molding a flange onto a tube'.*

Regarding claim 15: Hirsch et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft (elements 21, 42, 57) having rigidity and resists bending while in use (5:61-6:27 and Fig. 10); and forming a flange by onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (4:11-4:3 and Fig. 3 and 8). Hirsch et al. teaches that the hollow tubular shaft has a durometer in the range of 30-40 Shore A (6:10-17) and that the flexible connection flange portions have a durometer of 10-40 Shore A (4:31-39). Since the hardness range of the flange extends well below that of the tube, Hirsch et al. meet the instantly claimed limitation directed to material hardness.

Hirsch et al. does not forming a flange by molding onto a hollow tube. Nonetheless, Bodicky teaches molding a hub over a tube that has been inserted into a mold (Fig. 1 and 2:49-65). Hirsch et al. and Bodicky are combinable because they are both concerned with a similar technical difficulty, namely, connecting a plastic member to a plastic tube. At the time of invention a person having ordinary skill in the art would have found it obvious to have connected a molded portion to a tube, as taught by Bodicky, in the process of Hirsch et al., and would have been motivated to do so since Bodicky suggest such molding step provides a secure and fluid tight connection between plastic parts. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding alone would suggest a reasonable chance of success.

Regarding claims 16 and 17: Bodicky teaches molding about a tubular preform (Fig. 1 and 2:49-65) to form a desired structure (ie. a hub). A person having ordinary skill in the art would find it obvious to use a mold in the shape of a flange portion in order to form the structure of Hirsch et al. Hirsch et al. and Bodicky would be combined for the reasons as set forth above. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding (ie. thermal bonding) alone would suggest a reasonable chance of success.

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Regarding claim 18: Hirsch et al. teaches a flange/second material in the range of 10-40 Shore A (4:30-40), of which the upper portion of this range is "about 50".

Regarding claims 18 and 20: Hirsch et al. teaches the basic claimed process as set forth above. The rejection below of claim 18 is an alternative rejection, if the 10-40 Shore A range does not inherently teach "about 50".

Hirsch et al. does not a flange durometer of about 50 or a tube durometer of about 90-95. Nonetheless, the courts have held that the selection of a known material based upon its suitability for its intended use supports a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 65 USPQ 297 (1945). In the present case, Hirsch et al. teaches a range of material hardness suitable for a gastrostomy tube. However, the instant claim is readable upon a variety of medical ventilation tubes having flanges thereon (ie. catheters, antrostomy ventilation tubes, etc.). As such, a person having ordinary skill in the art would have found it obvious to have selected the appropriate material and material hardness for both a tube and flange through routine experimentation and optimization and have utilized such materials because Hirsch et al. suggests that tube must be maintain ventilation and the flange must be flexible enough to prevent premature removal but allow removal when desired while causing minimum trauma to the surrounding tissue.

Regarding claim 19: Hirsch et al. does not teach extruding a tube and cutting the tube to a predetermined length. Nonetheless, extruding a tube and cutting the tube to a predetermined length is well known in the extrusion art. At the time of invention a person having ordinary skill in the art would have found it obvious to have extruded a tube and cutting the tube to a predetermined length, as commonly practiced in the art, in the process of Hirsch et al., and would have been motivated to do so in order to provide an economical way of making various lengths of similar diameter tubing by using a single extrusion die instead of numerous closed molds.

Claim 23 is rejected under 35 U.S.C. 102(b) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) when taken with Vance, Jr. (*Insert Molding* – Article) or alternatively under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) in view of Bodicky (US Pat. 4,354,495) and Vance, Jr. (*Insert Molding* – Article).

Regarding claim 23: Hirsch et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft (elements 21, 42, 57) having rigidity and resists bending while in use (5:61-6:27 and Fig. 10); and forming a flange by

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onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (4:11-43 and Fig. 3 and 8). Hirsch et al. teaches that the hollow tubular shaft has a durometer in the range of 30-40 Shore A (6:10-17) and that the flexible connection flange portions have a durometer of 10-40 Shore A (4:31-39). Since the hardness range of the flange extends well below that of the tube, Hirsch et al. meet the instantly claimed limitation directed to material hardness.

Hirsch et al. specifically recites that the flanges and tubular portion may be attached to one another by insert molding (4:58-62). Vance Jr., provides evidence that 'insert molding' is a molding technique where a preform is inserted into a mold and another material is injection molded to encapsulate a portion of the preform. Vance Jr. states that insert molding is used quite extensively in the manufacture of medical devices, such as "insert molded needles hubs". A person having ordinary skill in the art would clearly understand that the hub is by the injected material. It is also noted that the flange structure of Hirsch et al. encapsulates an end portion of a tube (Fig. 3 and 8) and therefore a mold would inherently have a corresponding shape to hold a tubular preform and form the desired flange shape.

Alternatively, if Hirsch et al. does not forming a flange by molding onto a hollow tube. Nonetheless, Bodicky teaches molding a hub over a tube that has been inserted into a mold (Fig. 1 and 2:49-65). Hirsch et al. and Bodicky are combinable because they are both concerned with a similar technical difficulty, namely, connecting a plastic member to a plastic tube. At the time of invention a person having ordinary skill in the art would have found it obvious to have connected a molded portion to a tube, as taught by Bodicky, in the process of Hirsch et al., and would have been motivated to do so since Bodicky suggest such molding step provides a secure and fluid tight connection between plastic parts. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding alone would suggest a reasonable chance of success.

Bodicky teaches molding about a tubular preform (Fig. 1 and 2:49-65) to form a desired structure (ie. a hub). A person having ordinary skill in the art would find it obvious to use a mold in the shape of a flange portion in order to form the structure of Hirsch et al. Hirsch et al. and Bodicky would be combined for the reasons as set forth above. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the

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case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding (ie. thermal bonding) alone would suggest a reasonable chance of success.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Narayama et al. teaches insert molding a flange over a tube (Fig. 12 and 8:37-51).

Prichard et al. teaches uniting multiple preforms while injection molding a connecting part.

Patel et al. teaches insert molding a connector/hub over a catheter tube/lumen.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. However, the following comments apply:

Applicant's argument essentially alleges that the structure of Hirsch et al. is not insert molded because it does not connect (several) discrete parts. However, it is noted that the structure of Fig. 8 is only two main parts, a flange and tube, of which Hirsch et al. specifically prefers insert molding these components together (4:11-62). Although applicant's interpretation of insert mold is one form of 'insert molding' whereby multiple parts are united by molding a connecting part, it is strongly asserted that the broad art of insert molding also encompasses molding a single molded portion about a preform to unit the two parts as done in Hirsch et al.

Allowable Subject Matter

Claim 22 is allowed.

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach forming a flanged end portion and cutting that portion away and then molding another flange portion onto a tube.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaanni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Eashoo, Ph.D.
Primary Examiner
Art Unit 1732

5/19/04

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